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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/797,146	03/11/2004	Timothy Dinan	19280.007	4330

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EXAMINER	
PACKARD, BENJAMIN J	
ART UNIT	PAPER NUMBER
1612	

MAIL DATE	DELIVERY MODE
05/14/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/797,146	DINAN ET AL.	
	Examiner	Art Unit	
	Benjamin Packard	1612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 February 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3,5,7,10-20 and 22-29* is/are pending in the application.

4a) Of the above claim(s) *5,22 and 27* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) *1-3,7,10-20,23-26,and 28-29* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicants' arguments, filed 2/14/2008, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-4, 7, and 10-20 were rejected under 35 U.S.C. 103(a) as being unpatentable over Van West et al (Neuroendocrinology Letters, 1999, Vol.20, pp 11-17, see Applicants IDS dated 10/28/2005) in view of Sanchez (US Pregrant Pub 2004/0192764, see PTO-892 dated 11/15/2007) and Lanza et al (US 5,912,005, see PTO-892 dated 11/15/2007).

This rejection is maintained.

Examiner previously argued Van West et al teaches treating major depression using SSRI antidepressants and the anti-inflammatory effect of using such. Sanchez et al was cited to teach citalopram is a well known SSRI antidepressant which could be substituted into the composition and method of Van West et al. Finally, Lanza et al eas disclosed to teach the treatment of depression with a composition comprising ibuprofen. The combination of which would have been obvious to one of ordinary skill in the art where all compositions are used to treat the same condition, namely major depression.

Applicants argue Van West et al dose not disclose an effective amount of NSAID to treat or alleviate depression to a subject in need thereof. Additionally, Applicant argues the teaching of treating depression with ibuprofen is not proper.

Applicants note, on page 9 of the response dated 2/14/2008, “absence of allograft therapy, there are no teachings in the cited prior art to lead those of skill in the art to the use of ibuprofen in the methods as presently claimed.” The use of the "comprising" as a transition phrase make the claim inclusive, i.e. other components may be used in conjunction with the instantly claimed invention. Therefore, for the patient population who receive allograft therapy for the treatment of major depression, the motivation to treat using citalopram and ibuprofen, along with other compositions is obvious as previously explained. Therefore, any amount used in conjunction with allograft therapy can be construed an “effective” amount to treat or alleviate depression.

Further, Applicant’s argument that there is a difference between non-biological, non-invasive approach and cell-based composition approach is not persuasive. One of ordinary skill in the art would apply all known methods to treat a disease where the use of secondary drugs compliments the primary drug.

Claims 23-26 and 28-29 were rejected under 35 U.S.C. 103(a) as being unpatentable over Anisman et al (Annals of Medicine, 2003, Vol 35, pp 2-11, See PTO-892 dated 11/15/2007) in view of Van West et al (Neuroendocrinology Letters, 1999, Vol.20, pp 11-17, see Applicants IDS dated 10/28/2005), Sanchez (US Pregrant Pub 2004/0192764, see PTO-892 dated 11/15/2007), and Lanza et al (US 5,912,005, see PTO-892 dated 11/15/2007).

This rejection is maintained.

Examiner previously argued Anisman et al teach immunotherapy high doses of interleukin-2 and/or interferon induce depression and that theses depressive symptoms are attenuated by antidepressant treatment. Treatment would include a composition of citalopram and ibuprofen as explained above.

Applicants argue that Anisman et al does not remedy the lack of motivation to combine the composition from Van West et al, Sanchez, and Lanza et al.

Following the argument above, motivation does exist to combine the component for treatment of major depression. Where Anisman et al discloses major depression resulting from drug inducement, it would have been obvious to one of ordinary skill in the art use the method above for treating drug induced major depression.

Conclusion

No claims allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Benjamin Packard whose telephone number is 571-270-3440. The examiner can normally be reached on M-F 8-3:45 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick Krass can be reached on 571-272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Benjamin Packard/
Patent Examiner, Art Unit 1612

/Frederick Krass/
Supervisory Patent Examiner, Art Unit 1612